UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NADEZDA STEELE-WARRICK, individually and on behalf of all others similarly situated, Plaintiff vs. MICROGENICS CORPORATION AND THERMO FISHER SCIENTIFIC INC., Defendants	Hon. Vera M. Scanlon CASE 1:19-cv-06558-VMS **REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT MICROGENICS CORPORATION'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED CLASS ACTION COMPLAINT AND TO STRIKE CLASS ALLEGATIONS**

Plaintiff's opposition clarifies the far-fetched nature of her claims and confirms that Microgenics is entitled to dismissal. Plaintiff says she is pursuing recovery under *Landon v. Kroll Laboratory Specialists, Inc.* ("*Landon*"), 999 N.E.2d 1121 (N.Y. 2013). But the New York Court of Appeals limited *Landon* to its circumstances, which means the cause of action recognized there applies only to drug-testing laboratories that violate professionally accepted scientific testing standards. Here, however, while Microgenics supplied products and services for the New York Department of Corrections and Community Supervision ("DOCCS") to perform preliminary drug screens, Microgenics is not a laboratory and is not alleged to have violated any professionally accepted testing standards. Plaintiff has therefore failed to state a plausible claim for relief.

As to her class claim, Plaintiff proposes a peculiar theory in a transparent effort to sidestep Microgenics' standing and predominance challenges. She argues that any prisoner who received a positive result from a drug screen conducted on Microgenics-supplied equipment sustained injury *regardless* of whether the positive result was accurate and, in the case of a false positive result, *regardless* of the cause of the false positive. Her theory is that every positive drug screen caused injury even if the screen was accurate and the test subject was a committed drug abuser. Plaintiff

misunderstands the law. Even assuming some deficiency in the overall performance of the drug-screen system, drug-using prisoners who received accurate positive screens sustained no injury, and any prisoners who received false positive results must prove that Microgenics' alleged negligence caused their alleged harm. Plaintiff's response to Microgenics' standing and predominance challenges is meritless, and the class claim should be struck.

Law and Argument

I. The Complaint fails to state a plausible negligence claim under *Landon*.

Plaintiff is attempting to plead a claim under *Landon*. Pl.'s Opp'n 1, 9–17. In *Landon*, the New York Court of Appeals held that drug-testing laboratories hired to conduct drug tests of fluid samples from probationers face liability in tort directly to the probationers. Specifically, the court held—as an exception to the general rule that contractors do *not* owe tort duties to third parties—that drug-testing *laboratories* owe a "duty to the test subject to perform his drug test in keeping with relevant professional standards." *Landon*, 999 N.E.2d at 1124–25. Plaintiff accuses Microgenics of "seek[ing] to limit *Landon*," Pl.'s Opp'n 10, but the New York Court of Appeals has already done so, ruling that *Landon* is "limited" to cases involving "a drug laboratory's failure to adhere to professionally accepted scientific standards in the testing of the biological sample.'" *Pasternack v. Lab. Corp. of Am. Holdings*, 59 N.E.3d 485, 490 (N.Y. 2016). Thus, liability arises only if the defendant is a drug-testing laboratory and it violated professionally accepted scientific testing standards. Under this framework, Plaintiff has not plausibly alleged duty or breach.

A. Plaintiff has not plausibly alleged that Microgenics owed her a duty of care.

1. Plaintiff has not pleaded that Microgenics is a drug-testing laboratory.

Microgenics entered into a contract with DOCCS to supply urinalysis analyzers, immunoassays, and related services. Compl. [ECF 31] ¶¶ 2, 9. Plaintiff does not allege—nor could

she—that Microgenics is a laboratory or that it conducts laboratory testing. She argues instead that Microgenics is "[l]ike" a laboratory. Pl.'s Opp'n 10. But the attempted similitude simply does not hold, legally or factually. *Landon* imposes a duty on laboratories, not entities deemed *like* a laboratory. In fact, while many courts have imposed tort duties in negligence on drug-testing *laboratories*, *see* Pl.'s Opp'n 17 n.5, Microgenics is not aware of any court anywhere that has imposed such a duty on a drug-testing *equipment supplier*. Nor apparently is Plaintiff aware of any such cases.[1] Her request that the Court extend *Landon* to apply to an equipment supplier would establish a duty not previously recognized in this state or any other.

Further, the suggestion that Microgenics is *like* a laboratory is meritless. Laboratories are rigorously controlled testing facilities. *E.g.*, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 73 Fed. Reg. 71,858, 71,878 (Nov. 25, 2008) (defining "laboratory" as a "permanent location where initial and confirmatory testing, reporting of results, and recordkeeping is performed under the supervision of a responsible person"). Plaintiff does not allege that Microgenics is such a facility or that Microgenics performed or supervised testing. By Plaintiff's admission, DOCCS—not Microgenics—conducted her drug screen. Compl. ¶ 61.

Plaintiff argues that by supplying training and maintenance services, Microgenics played a "constant role" in the drug screens DOCCS conducted.[2] Pl.'s Opp'n 10. Even if true, that would not support liability under *Landon* because it would not change the fact that Microgenics is not a laboratory. But it isn't true that Microgenics played a "constant role" in DOCCS's drug screens.

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[1] While Plaintiff notes that one court permitted a Section 1983 claim to proceed against a drug-test manufacturer in *Amig v. Cty. of Juniata*, 432 F. Supp. 3d 481 (M.D. Pa. 2020), Pl.'s Opp'n 11 n.4, the plaintiff there did *not* even attempt to plead a negligence claim.

[2] Plaintiff refers to allegations in a pleading filed in another case by DOCCS and to unidentified documents produced to her. Pl.'s Opp'n 10 n.3, 11. The intended import is unclear, but regardless, Plaintiff "cannot amend [he]r complaint through arguments in a brief." *Johnson v. Levy*, No. 10-CV-3217 (ADS)(ETB), 2012 WL 3580236, at *6 (E.D.N.Y. Aug. 17, 2012) (citation omitted).

Microgenics' training commitments were to provide one-time training at each facility and annual master training to select personnel. Contract No. CC161458 [Ex. 1 to Marcusen Decl. in Support of Microgenics Mot. to Dismiss ("Marcusen Decl.")], App. H, at 2. As to maintenance, Microgenics agreed to provide preventive maintenance once per year with other onsite service visits only as needed. *Id.* Such infrequent activities hardly qualify as "constant" involvement. To the contrary, DOCCS's own policy for drug screens confirms that DOCCS itself conducts the screens without assistance. DOCCS Directive No. 4937 [Ex. 4 to Marcusen Decl.] at 1–6.

In short, Microgenics is not a laboratory or even *like* a laboratory. And consequently, the duty of care recognized in *Landon* does not apply to Microgenics.

2. Plaintiff has not pleaded any relevant scientific testing standards.

Plaintiff insists she has pleaded the existence of relevant professionally accepted scientific standards. Pl.'s Opp'n 11–13. She manifestly has not. Under *Landon*, the standard at issue must be "'professionally accepted'" and must implicate the "scientific integrity of the testing process." *Pasternack*, 59 N.E.3d at 490. Such standards typically will be found in statutes or regulations. *See Braverman v. Bendiner*, 121 A.D.3d 353, 359, 990 N.Y.S.2d 605, 611 (2d Dep't 2014) (*Landon* requires "reference to statutory, regulatory, or professional standards"). For instance, in *Landon*, the plaintiff alleged the defendant's testing violated formal government standards—federal cutoff levels and state requirements for confirmatory testing. *Landon*, 999 N.E.2d at 1123.

Plaintiff cites nothing approaching the type of professionally accepted drug-testing standards contemplated by *Landon*. Instead, she seizes on two boilerplate provisions in Microgenics' contract with DOCCS: that products supplied "would be 'substantially uninterrupted or error-free in operation'" and that the products "would 'conform to the manufacturer's specifications, performance standards, and documentation.'" Pl.'s Opp'n 12. Those generic

requirements are not found in any federal or state regulations or guidelines or industry standards. They are excerpts from the general terms and conditions applicable to every DOCCS procurement contract, regardless of the goods being procured. Contract No. CC161458 [Ex. 1], App. B, at 1. They do not so much as allude to drug testing or to testing standards. *See id.* at 1–18.

Alternatively, Plaintiff contends Microgenics violated its "own standards." Pl.'s Opp'n 12. Recounting that immunoassay drug screens provide only preliminary results and that Microgenics' product literature recommends confirmatory testing (facts of which DOCCS was aware, Microgenics' Mem. 3–6), Plaintiff asserts that Microgenics violated its own recommendation by supposedly testifying that DOCCS could impose discipline without confirmatory testing. Pl.'s Opp'n 12. Her argument is meritless. Even if the recommendation for confirmatory testing were a professionally accepted standard (Plaintiff says its Microgenics' "own" standard), it does not apply to *testing*; it pertains rather to the *use* of test results. *See Pasternack*, 59 N.E.3d at 491 (refusing to extend *Landon* to alleged standards "unrelated to the actual performance of scientific testing of the biological sample"). Furthermore, and decisively, Microgenics could not have violated the recommendation as to Plaintiff because it did *not* testify at her hearing. Pl.'s Opp'n 19 n.8.

Despite her adamance to the contrary, Plaintiff has not plausibly alleged a duty of care under *Landon* because she has not identified a professionally accepted scientific testing standard.

B. Plaintiff has not plausibly alleged a breach of duty.

Breach under *Landon* consists of the violation of a professionally accepted testing standard. *Landon*, 999 N.E.2d at 1124–25. Plaintiff offers conclusory assertions about Microgenics' supposed failings, Pl.'s Opp'n 18, but none involves violation of an accepted testing standard.

Plaintiff argues that because breach generally poses a fact question, it "cannot be resolved at the pleading stage." *Id.* at 17 (citation omitted). Microgenics is not, however, asking the Court

to resolve a fact dispute; it seeks dismissal on the ground that the Complaint lacks plausible allegations of fact from which breach could be inferred. Such a challenge is entirely proper. *See Nelson v. Publishers Circulation Fulfillment, Inc.*, No. 11 Civ. 1182 (TPG), 2012 WL 760335, at *6 (S.D.N.Y. Mar. 7, 2012) (finding that plaintiff failed plausibly to allege breach).

II. Plaintiff's class allegations should be struck as no class could be certified.

Contrary to Plaintiff's hyperbolic contentions, *see* Pl.'s Opp'n 20–21, motions to strike class allegations, while viewed cautiously, are nonetheless appropriate where it "would be impossible to certify the alleged class regardless of the facts Plaintiffs may be able to obtain during discovery." *Mayfield v. Asta Funding, Inc.*, 95 F. Supp. 3d 685, 696 (S.D.N.Y. 2015); *see also Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 949 (6th Cir. 2011) (affirming striking of class allegations where no further discovery would rescue class claims). Such is the case here.

A. The proposed class includes members who lack standing, and Plaintiff's proffered work-around is factually and legally untenable.

As a threshold issue, "no class may be certified that contains members lacking Article III standing." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006). Class-member standing is generally analyzed as an Article III question and addressed prior to reaching any Rule 23 analysis. *See, e.g.*, *Tomassini v. FCA US LLC*, 326 F.R.D. 375, 385 (N.D.N.Y. 2018) (addressing absent class member standing before reaching Rule 23 analysis). Plaintiff is therefore wrong when she says that Microgenics "does not even pretend that the grounds for its motion to strike are distinct from the class-certification factors." Pl.'s Opp'n 21. Standing is distinct from, and antecedent to, the Rule 23 analysis. And when the proposed class includes members who suffered no injury, the class allegations may be struck at the outset. *See Cashatt v. Ford*, Case No. 3:19-cv-05886-RBL, 2020 WL 1987077, at *5 (W.D. Wash. Apr. 27, 2020) (striking class allegations for lack of standing because the complaint did not allege—and "common sense does not suggest"—

that all users of the vehicle class experienced the alleged defect); *Hernandez v. State Farm Fire & Cas. Co.*, Case No. 16cv-200-LAB (JLB), 2017 WL 932198, at *4 (S.D. Cal. Mar. 9, 2017) (noting lack of standing for class members who suffered no injury as sufficient basis to strike class claims); *Colley v. Procter & Gamble Co.*, Case No. 1:16-cv-918, 2016 WL 5791658, at *8–9 (S.D. Ohio Oct. 4, 2016) (striking class allegations because proposed class included uninjured class members).

Microgenics showed that the proposed class is uncertifiable because it would be comprised of numerous members who lack standing: prisoners who abused drugs, received accurate positive drug-screen results, and thus suffered no injury in fact. Microgenics' Mem. 17–19. Rather than attempt to narrow the class to resolve this facially apparent obstacle, Plaintiff leaps to a novel injury theory the Court should reject out of hand. She contends that all prisoners (even ardent drug users) who received positive drug screens sustained injury *regardless* of whether the results were accurate. In other words, her proposition is that, because Microgenics' analyzers allegedly produced false positive results in some cases, anyone who received a positive result—including an accurate positive result—necessarily suffered injury. The theory is completely unfounded.

First, Plaintiff's new injury theory is inconsistent with her own pleading. Throughout her Complaint, Plaintiff framed her class claim in terms of injury arising from allegedly false-positive drug screens. *See, e.g.*, Compl. ¶ 97 (including false-positive screens as an element of alleged commonality); *id.* ¶ 99 (identifying false-positive screens as an element of alleged typicality); *id.* ¶ 108 (positing false-positive screens as the operative factual basis for the class's alleged injuries). By contrast, the Complaint nowhere suggests that accurate screens constitute or cause injury.

Second, and much more importantly, Plaintiff's newfound theory finds not even a modicum of support in the case law. It is well-recognized that mere exposure to or use of an allegedly unreliable product or service does not alone create a recoverable injury where the product or

service in question performed satisfactorily *for the given plaintiff*. *See Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) ("[I]t is not enough for a plaintiff to allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must allege that *their* product *actually exhibited* the alleged defect." (internal quotation marks and citations omitted)); *Walewski v. Zenimax Media, Inc.*, 502 F. App'x 857, 861 (11th Cir. 2012) (affirming district court's denial of certification where plaintiff's proposed class included users who never experienced the alleged defect.); *Feinstein v. Firestone Tire & Rubber Co.*, 535 F. Supp. 595, 603 (S.D.N.Y. 1982) (no cause of action where alleged defect never manifested); *Frank v. DaimlerChrysler Corp.*, 292 A.D.2d 118, 121–28, 741 N.Y.S.2d 9, 12–17 (1st Dep't 2002) (rejecting negligent-design claim because the product did not malfunction).

Plaintiff tellingly fails to cite a single court decision holding or even suggesting that mere exposure to an allegedly unreliable drug-screen system somehow causes injury even in those who receive true and accurate drug-screen results. Nor is Microgenics aware of any such cases. Rather, as noted above, the consensus view across jurisdictions is that mere use or exposure to an allegedly unreliable product or service does *not* create an actionable injury.

By seeking a class that encompasses all positive test results *regardless* of their accuracy as to individual class members, Plaintiff ensures that any certified class would include members who lack standing. *See Spence v. Farrier*, 807 F.2d 753, 755 (8th Cir. 1986) ("The unauthorized use of narcotics is a problem that plagues virtually every penal and detention center in the country." (citation omitted)). Moreover, this is not an issue that could be cured through discovery or tinkering with the class definition. Plaintiff's legal theory presents an abstract question of law the Court can decide now. And because the contention that true positive drug screens inflict injury is inconsonant with the existing law, the Court should reject Plaintiff's theory and strike the class allegations.

B. The Court should strike the class allegations for lack of predominance as well.

Microgenics demonstrated why this is the sort of case in which the Court can ascertain at the pleading stage that individual issues will predominate: the necessity of distinguishing between false positive and accurate positive results, as well as the necessity to establish that any false positive occurred due to a negligence-induced problem with Microgenics' products or services as opposed to other causes, such as a failure on the part of the DOCCS personnel conducting the screens across 52 different correctional facilities. *See* Microgenics' Mem. 22–25. As to every class member, complex issues of injury and causation would require highly individualized inquiries into matters such as (i) the evidence corroborating the positive drug screen (e.g., testimonial evidence that the prisoner was seen using drugs or appeared intoxicated or physical evidence such as drug paraphernalia), (ii) whether DOCCS personnel properly collected, handled, and processed the urine specimen, (iii) whether DOCCS personnel properly maintained and used the Microgenics analyzers and immunoassays in accordance with written instructions and training; and (iv) whether DOCCS personnel properly investigated cross-reactivity issues as required to do by statute. *See* DOCCS Directive No. 4937 [Ex. 4] at 2–6 (outlining DOCCS's procedure for drug screens).

Those complex injury and causation issues are evident at the pleading stage, establishing that predominance could never be achieved and that the class allegations should be struck. *See Jones v. BRG Sports, Inc*., No. 18 C 7250, 2019 WL 3554374, at *5–6 (N.D. Ill. Aug. 1, 2019) (striking class allegations on the face of the pleadings because individualized questions of injury and causation predominated). In fact, Plaintiff does not even dispute that, if required to prove causation and injury as traditionally required for a common-law negligence claim, individual issues would predominate over any purported common questions. Pl.'s Opp'n 23–24.

Instead, as with the issue of standing, Plaintiff proposes to deviate from settled law to effectively eliminate causation and injury as elements for each class member's claim. Plaintiff would have the Court recognize a new cause of action in which mere exposure to a drug-screen system that allegedly causes unreliable results in some cases causes injury in all cases. As Plaintiff sees it, every class member may recover if he or she received a positive drug screen, without any requirement to show that the screen was inaccurate or that any inaccuracy was caused by Microgenics' alleged negligence. Pl.'s Opp'n 23–24. Not surprisingly, Plaintiff cites no authority for the absolute liability she proposes. Microgenics could find only one case involving a similar argument, and the court there resoundingly rejected it. *See Baker v. Abo*, Civ. No. 01-1248 JRTJSM, 2003 WL 21639151, at *3 (D. Minn. July 2, 2003) (rejecting liability premised on improper test procedures without evidence the irregularity produced an incorrect test).

As with standing, scrutiny of Plaintiff's untenable path to establishing predominance presents a legal issue the Court can resolve now without costly and time-consuming discovery. Contrary to Plaintiff's contention, recovery for each class member would require individualized proof of injury (a false positive, among other things)[3] and causation (negligence of Microgenics as opposed to DOCCS's or the class member's conduct or expected cross-reactivity), and Plaintiff offers no suggestion how such fact-bound issues could be resolved on a class-wide basis. Where, as here, discovery would not rehabilitate the class claims, striking the class allegations is proper.

Conclusion

For all the reasons stated, Defendant Microgenics Corporation respectfully requests that the Court grant its motion to dismiss the Complaint and strike Plaintiff's class allegations.

[3] Because cross-reactivity is always a potential to be investigated by DOCCS (in accordance with its own procedural directives), a false positive result, without more, would not necessarily constitute or cause injury.

Respectfully submitted,

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s/Nathan J. Marcusen

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